[Billing Code 4140-01-P]

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**National Institutes of Health** 

Prospective Grant of Start-Up Exclusive Patent License Agreement: Treatment of Breast

Cancer, Prostate Cancer, Ewing Sarcoma, and Thymoma

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Patent License Agreement to Paris Therapeutics, a company having a place of business in Santee, CA, to practice the inventions embodied in the following patent applications:

- U.S. Provisional Patent Application. No. 61/474,664, filed April 12, 2011
  HHS Ref. No.: E-068-2011/0-US-01
  Titled: Human Monoclonal Antibodies that bind insulin-like growth factor (IGF) I and II
  Inventors: Dimiter S. Dimitrov (NCI), Qi Zhao (NCI), and Zhongyu Zhu (NCI)
- PCT Application No. PCT/US2012/033128, filed April 11, 2012
  HHS Ref. No.: E-068-2011/0-PCT-02
  Titled: Human Monoclonal Antibodies that bind insulin-like growth factor (IGF) I and II
  Inventors: Dimiter S. Dimitrov (NCI), Qi Zhao (NCI), and Zhongyu Zhu (NCI)
- 3. U.S. Patent Application No. 14/111,507, filed October 11, 2013 HHS Ref. No.: E-068-2011/0-US-03 Titled: Human Monoclonal Antibodies that bind insulin-like growth factor (IGF) I and II Inventors: Dimiter S. Dimitrov (NCI), Qi Zhao (NCI), and Zhongyu Zhu (NCI)

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Patent License Agreement may be worldwide, and the field of use may be limited to "Antibodies against Insulin-like Growth Factors IGF-I and IGF-II for the treatment of breast cancer, prostate cancer, Ewing sarcoma, and thymoma."

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application(s), inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Patent License Agreement should be directed to: Whitney A. Hastings, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; E-mail: <a href="mailto:hastingw@mail.nih.gov">hastingw@mail.nih.gov</a>. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

**SUPPLEMENTARY INFORMATION:** This technology describes fully human monoclonal antibodies that have been affinity maturated against IGF-I and IGF-II and display extremely high affinities for IGF-I and IGF-II in the picoM range. Some of these antibodies potently inhibited signal transduction mediated by the IGF-1R interaction with IGF-I and IGF-II and blocked phosphorylation of IGF-IR and the insulin receptor. In addition, they inhibited migration in the MCF-7 breast cancer cell line at the picoM range. Therefore, these antibodies could be used to

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prevent binding of IGF-I and/or IGF-II to its concomitant receptor IGFIR, consequently,

modulating diseases such as cancer.

The prospective Start-Up Exclusive Patent License Agreement is being considered under

the small business initiative launched on October 1, 2011 and will comply with the terms and

conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective Start-Up Exclusive Patent

License Agreement may be granted unless the NIH receives written evidence and argument,

within fifteen (15) days from the date of this published notice, that establishes that the grant of

the contemplated Start-Up Exclusive Patent License Agreement would not be consistent with the

requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are filed in

response to this notice will be treated as objections to the grant of the contemplated Start-Up

Exclusive Patent License Agreement. Comments and objections submitted to this notice will not

be made available for public inspection and, to the extent permitted by law, will not be released

under the Freedom of Information Act, 5 U.S.C. 552.

Dated: March 13, 2014.

Richard U. Rodriguez,

Director,

Division of Technology Development and Transfer,

Office of Technology Transfer,

National Institutes of Health.

Date: 03/18/2014]

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